



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,498	07/07/2003	Alan P. Kozikowski	9328-051-999	8108

25181 7590 11/24/2006

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER

DESAI, RITA J

ART UNIT	PAPER NUMBER
----------	--------------

1625

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,498

Applicant(s)

KOZIKOWSKI ET AL.

Examiner

Rita J. Desai

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,32,41,50,60-62,64,73-81,90 and 91 is/are pending in the application.
- 4a) Of the above claim(s) 41,50,60-62,64,73-81,90 and 91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8 and 32 , Groups I and III are rejoined in part..

Claims 1, 41, 50, 60-62, 64, 73-81, and 90-91 have been amended to conform to the rejoined Groups elected in response to the Restriction Requirement.

Method claims 41, 50, 60-62, 64, 73-81, and 90-91 are withdrawn till the compounds claims are allowable.

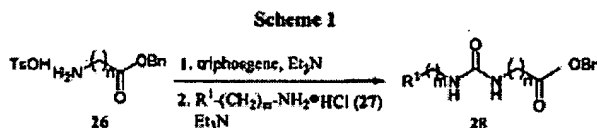
Claims 9-31, 33-40, 42-49, 52-59, 65-72, and 82-89 were drawn to non-elected groups and have been canceled.

Response to the Arguments:-

The rejection of claims 1-8 and 32 under 35 USC 112 first paragraph still stands.

Applicants argue that

The synthetic Scheme 1 (page 31 of the instant Application; reproduced in pertinent part below), wherein the Applicants provide a straightforward synthetic approach to the desired urea compounds of the invention via reaction (in step 2) of a primary amine with an electrophilic isocyanate intermediate (formed in step 1).



Art Unit: 1625

This is not convincing because the rejection is based on 2 parts, make and use. The use of these compounds in pharmaceutical uses is highly unpredictable and as such the applicants should have enable them.

Applicants argue that on pages 70-85 in table 3 and 4 applicants have provided a lot of data to demonstrate inhibition.

This may be so, however all the compounds shown have either a phenyl or an admantyl, and this does not cover the scope of applicants generic claims of the aryl cycloalkyl or 3 to 10 membered hetero cycle.

Thus the rejection still stands.

The rejection of claims 1-8 and 32 still stands.

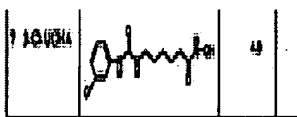
Solely on the Richon et al reference the compounds are homologs with a difference of one -CH₂- group.

Applicants argument that this is an oversimplification is not correct.

If the compound 7 of the Richon reference is compare to the compounds, it reads on the compounds when, R₁ is a phenyl m is 0, and n is 5.

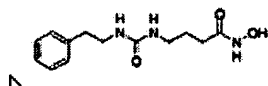
Thus the difference is only of m being more 1.

Richons compounds is



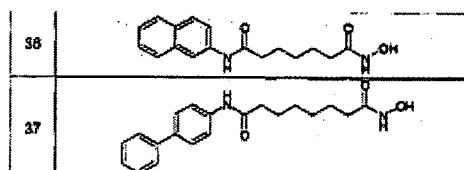
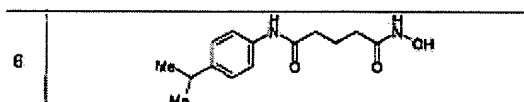
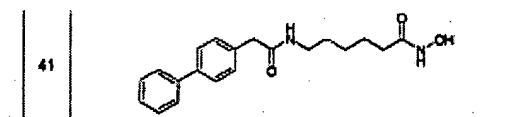
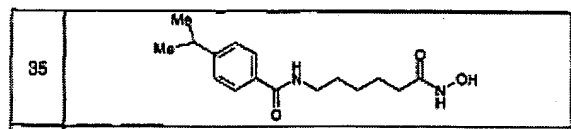
Art Unit: 1625

Applicants compound is



Similar compounds in WO 0226696 Watkins et al are also taught.

The WO patent teaches the compounds



Clearly the equivalency of the linkage to the N or the Ch2 for the R1 is equivalent.

The compounds have a similar activity i.e. are HDAC inhibitors. And with the teaching of the equivalence of the linkages, there is a motivation to modify them to obtain the compounds of the invention.

* It should be noted that applicants own specifications teaches compounds which have m is 0 and they show similar properties. It is a clear validation of the examiners arguments.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

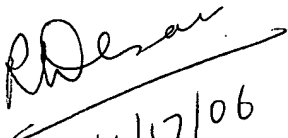
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625


11/17/06

R.D.
November 17, 2006